IEC 60601-2-54

Edition 1.0 2009-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

Appareils électromédicaux –
Partie 2-54: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X utilisés pour la radiographie et la radioscopie

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-2-54 has been prepared by IEC subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

IEC 60601-2-54 has been developed for use with the third edition of IEC 60601-1 (2005). It replaces and supersedes IEC 60601-2-7 and IEC 60601-2-32, as well as IEC 60601-2-28:1993 (currently under revision), all of which were developed to amend earlier editions of IEC 60601-1 and consequently no longer apply to this particular standard.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62B/735/FDIS	62B/750/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

The contents of the corrigenda of March 2010 and June 2011 have been included in this copy.

INTRODUCTION

This particular standard has been prepared to provide, based on IEC 60601-1:2005 (third edition) and its collaterals, a complete set of safety requirements for ME EQUIPMENT for RADIOGRAPHY and RADIOSCOPY. While the previously existing standards for such equipment were dedicated to components and subsystems, this particular standard addresses the system level of X-RAY EQUIPMENT, which consists of a combination of an X-RAY GENERATOR, ASSOCIATED EQUIPMENT and ACCESSORIES. Component functions are addressed as far as necessary.

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of ME EQUIPMENT for RADIOGRAPHY and RADIOSCOPY. Requirements for additional provisions for ME EQUIPMENT for interventional applications are covered by IEC 60601-2-43.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS intended to be used for projection RADIOGRAPHY and RADIOSCOPY. IEC 60601-2-43 applies to ME EQUIPMENT and ME SYSTEMS intended to be used for interventional applications and refers to applicable requirements in this particular standard.

ME EQUIPMENT and ME SYSTEMS intended to be used for bone or tissue absorption densitometry, computed tomography, mammography or dental applications are excluded from the scope of this International Standard. The scope of this International Standard also excludes radiotherapy simulators.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

NOTE Taking into account economic and social factors, the scope of this particular standard includes ME EQUIPMENT intended to be used for DIRECT RADIOSCOPY. In some countries examinations performed with DIRECT RADIOSCOPY are prohibited.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ME EQUIPMENT and ME SYSTEMS for RADIOGRAPHY and RADIOSCOPY.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203 respectively. IEC 60601-1-8 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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[1] The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

NOTE OPERATORS of X-RAY EQUIPMENT are used to audible signals as required in this particular standard rather than to the concepts of IEC 60601-1-8. Therefore IEC 60601-1-8 does not apply.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography on page 64.

Clause 2 of the general standard applies, except as follows:

Addition:

IEC 60336, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60580:2000, *Medical electrical equipment – Dose area product meters*

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 60806, *Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis*

IEC 62220-1:2003, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1: Determination of the detective quantum efficiency*

Amendment:

IEC 60601-1-2:2007 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-3:2008 *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, applicable collateral standards and IEC 60788:2004 apply, except as follows:

NOTE An index of defined terms is found beginning on page 65.

Addition:

201.3.201
DIRECT RADIOGRAPHY
RADIOGRAPHY in which the permanent recording is effected at an IMAGE RECEPTION AREA

Example: film-screen or film radiography.

201.3.202
DIRECT RADIOSCOPY
RADIOSCOPY in which the visible images are presented at the IMAGE RECEPTION AREA, or close to it, in the RADIATION BEAM

201.3.203
DOSE AREA PRODUCT
product of the area of the cross-section of an X-RAY BEAM and the averaged AIR KERMA over that cross-section. The unit is the gray square metre ($Gy \cdot m^2$)

201.3.204
ENTRANCE FIELD SIZE
dimensions of the field in the entrance plane of an X-RAY IMAGE RECEPTOR that can be used for the transmission of an X-RAY PATTERN under specific conditions

201.3.205
INDIRECT RADIOGRAPHY
RADIOGRAPHY in which the permanent recording is effected after TRANSFER of the information obtained at an IMAGE RECEPTION AREA

Examples: CR systems, digital detector systems, image intensifier systems.

201.3.206
INDIRECT RADIOSCOPY
RADIOSCOPY in which the images are presented at a location outside the RADIATION BEAM after TRANSFER of the information

201.3.207
INTERLOCK
means preventing the start or the continued operation of ME EQUIPMENT unless certain predetermined conditions prevail

201.3.208
NOMINAL SHORTEST IRRADIATION TIME
shortest LOADING TIME for which a required constancy of the controlled RADIATION QUANTIY is maintained

NOTE The IRRADIATION TIME is controlled by a HIGH-VOLTAGE GENERATOR with AUTOMATIC CONTROL SYSTEMS.

201.3.209
SERIAL RADIOGRAPHY
RADIOGRAPHY in which the information is obtained and recorded in a regular or irregular series of LOADINGS with equal or unequal LOADING FACTORS

201.4 General requirements

Clause 4 of the general standard applies, except as follows

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Accuracy of LOADING FACTORS	203.6.4.3.104
Reproducibility of the RADIATION output	203.6.3.2
AUTOMATIC CONTROL SYSTEM	203.6.5
Imaging performance	203.6.7

201.4.10.2 Supply mains for ME EQUIPMENT and ME SYSTEMS

Addition:

The internal impedance of a SUPPLY MAINS is to be considered sufficiently low for the operation of X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY if the value of the APPARENT RESISTANCE OF SUPPLY MAINS does not exceed the value specified in the ACCOMPANYING DOCUMENTS.

Either the APPARENT RESISTANCE OF SUPPLY MAINS or other appropriate SUPPLY MAINS specifications used in a facility shall be specified in the ACCOMPANYING DOCUMENTS.

NOTE If a NOMINAL voltage is claimed for a mains power supply system, it is assumed that there is no voltage of a higher value between any of the conductors of the system or between any of these conductors and earth.

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ± 2 % of the peak value of the ideal waveform.

A three-phase SUPPLY MAINS is considered to have a practical symmetry if it delivers symmetrical voltages and produces, when loaded symmetrically, symmetrical currents.

The requirements of this standard are based upon the assumption that three-phase systems have a symmetrical configuration of the MAINS VOLTAGE with respect to earth. Single-phase systems may be derived from such three-phase systems. Where the supply system is not earthed at the source it is assumed that adequate measures have been provided to detect, limit and remedy any disturbance of symmetry within a reasonably short time.

X-RAY EQUIPMENT is considered to comply with the requirements of this standard only if its specified NOMINAL ELECTRIC POWER can be demonstrated at an APPARENT RESISTANCE OF SUPPLY MAINS having a value not less than the APPARENT RESISTANCE OF SUPPLY MAINS specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.7 Electrical input power from the SUPPLY MAINS

Addition:

For ME EQUIPMENT that is specified to be PERMANENTLY INSTALLED, the information may be stated in the ACCOMPANYING DOCUMENTS only.

The information on the input power shall be specified in terms of combinations of

a) the RATED MAINS VOLTAGE of the ME EQUIPMENT in volts; see 7.2.1 and 7.2.6 of the general standard,
b) the number of phases; see 7.2.1 and 7.2.6 of the general standard,
c) the frequency, in hertz; see 7.2.1 and 7.2.6 of the general standard,
d) the maximum permissible value for APPARENT RESISTANCE OF SUPPLY MAINS, in ohms;
e) the characteristics of OVER-CURRENT RELEASES required in the SUPPLY MAINS.

NOTE These requirements are adapted from 6.1j) of IEC 60601-2-7:1998.

201.7.2.15 Cooling conditions

Addition:

If cooling is necessary for safe operation of ME EQUIPMENT, or a subassembly thereof, the cooling requirements shall be indicated in the ACCOMPANYING DOCUMENT, including as appropriate:

– the maximum heat dissipation into the surrounding air, given separately for each subassembly that dissipates more than 100 W and might be separately located on installation;

– the maximum heat dissipation into forced air cooling devices, and the corresponding flow rate and temperature rise of the forced air stream;

– the maximum heat dissipation into a cooling medium utility and the permissible input temperature range, minimum flow rate and pressure requirements for the utility.

NOTE These requirements are adapted from 6.1t) of IEC 60601-2-7:1998.

Additional subclause:

201.7.2.101 Beam limiting device

BEAM LIMITING DEVICES shall be provided with the following markings:

– those required in subclause 7.2.2 of the general standard;

– serial designation or individual identification;

– TOTAL FILTRATION in terms of QUALITY EQUIVALENT FILTRATION.

NOTE These requirements are adapted from 6.1 of IEC 60601-2-28:1993.

201.7.8.1 Colours of indicator lights

Addition:

The indication of X-RAY related states shall be excluded from subclause 7.8 in the general standard. Subclauses 203.6.4.2 and 203.6.4.101 shall apply instead.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall contain quality control procedures to be performed on the X-RAY EQUIPMENT by the RESPONSIBLE ORGANISATION. These shall include acceptance criteria and frequency for the tests.

Additionally for X-RAY EQUIPMENT provided with an integrated digital X-RAY IMAGE RECEPTOR, the ACCOMPANYING DOCUMENTS shall contain:

– a description of image processing applied to ORIGINAL DATA including the revision number or how to determine it and identification of the version if applicable;

– a description of the file transfer format of the images acquired with this unit and of any data associated with these images;

The performance of means required to present the images for diagnostic purpose shall be stated according to the INTENDED USE.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Addition:

201.7.9.2.1.101 LOADING FACTORS

In the instructions for use the LOADING FACTORS shall be stated as described below. The following combinations and data shall be stated:

a) The corresponding NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY and RADIOGRAPHY together with the highest X-RAY TUBE CURRENT obtainable from the ME EQUIPMENT when operated at that X-RAY TUBE VOLTAGE.

b) The corresponding highest X-RAY TUBE CURRENT for RADIOSCOPY and RADIOGRAPHY together with the highest X-RAY TUBE VOLTAGE obtainable from the ME EQUIPMENT when operating at that X-RAY TUBE CURRENT.

c) The corresponding combination of X-RAY TUBE VOLTAGE for RADIOSCOPY and RADIOGRAPHY, and X-RAY TUBE CURRENT which results in the highest electric power in the high-voltage circuit (see 203.4.101).

d) The NOMINAL ELECTRIC POWER given as the highest constant electric power in kilowatts which the ME EQUIPMENT can produce/generate, for a LOADING TIME of 0,1 s at an X-RAY TUBE VOLTAGE of 100 kV or, if these values are not selectable, with nearest parameters (see 203.4.101).

   The NOMINAL ELECTRIC POWER shall be given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and the LOADING TIME.

e) For ME EQUIPMENT indicating precalculated or measured CURRENT TIME PRODUCT, the lowest CURRENT TIME PRODUCT or the combinations of LOADING FACTORS resulting in the lowest CURRENT TIME PRODUCT.

   If the value of the lowest CURRENT TIME PRODUCT depends upon the X-RAY TUBE VOLTAGE or upon certain combinations of values of LOADING FACTORS, the lowest CURRENT TIME PRODUCT may be given as a table or curve showing the dependence.

f) The NOMINAL SHORTEST IRRADIATION TIME used in AUTOMATIC EXPOSURE CONTROL systems of ME EQUIPMENT.

   If the NOMINAL SHORTEST IRRADIATION TIME depends upon LOADING FACTORS such as X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT, the ranges of these LOADING FACTORS for which the NOMINAL SHORTEST IRRADIATION TIME is valid shall be stated.

   The maximum possible range of the X-RAY TUBE VOLTAGE and/or the X-RAY TUBE CURRENT during IRRADIATIONS, controlled with the AUTOMATIC EXPOSURE CONTROL SYSTEMS, shall be stated in the instructions for use.

NOTE These requirements are adapted from 6.8.2 a) of IEC 60601-2-7:1998.

201.7.9.2.1.102 X-RAY SOURCE ASSEMBLY

The instructions for use shall state the maximum symmetrical RADIATION FIELD of the integrated X-RAY SOURCE ASSEMBLY determined according to IEC 60806.

NOTE This requirement is adapted from 6.8.2 (dd) of IEC 60601-2-28:1993.

201.7.9.2.1.103 Integrated X-RAY IMAGE RECEPTOR

For X-RAY EQUIPMENT provided with an integrated X-RAY IMAGE RECEPTOR, the instructions for use shall contain a description of the particular handling and maintenance of the X-RAY IMAGE RECEPTOR.

Compliance is checked by inspection of the instructions for use.